510(K) Summary

1. Name of Submitter:

Hospira, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045

Owner/Operator # 9063339

2. Manufacturer and Establishment Registration Number:

Hospira, Inc. – Morgan Hill
755 Jarvis Drive
Morgan Hill, CA 95037

Establishment Registration # 2921482

3. Proprietary or Trade Name of Proposed Device: Hospira GemStar® I.V. Infusion Pump

4. Common Name: Infusion Pump

5. Device Classification, Pancode and ProCode: Class II, 80-FRN (Infusion Pump)
Class II, 80-FPA (Administration Sets)

6. Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for intravenous infusion pumps. Infusion pumps are listed in 21 CFR 880.5725.

7. Intended Use:
The Hospira GemStar® IV Infusion Pump is intended for use in intravenous, arterial, short-term epidural, and parenteral administration of general I.V. fluids, medications, nutritionals fluids, and blood/blood products to patients.

8. Indications for Use:
The Hospira GemStar® Infusion Pump System with Hospira GemStar Connect™ is intended for use in Intravenous (central line or peripheral access), arterial, subcutaneous, short term epidural infusion and parenteral administration of general I.V. fluids, medications, nutritional fluids, and blood/blood products.

The indications for use include hospital, ambulatory, and home care environments. The pump must be used with sterile, dedicated, GemStar® administration sets.

9. Proposed Device Description:
The Hospira GemStar® Infusion Pump Systems are a family of single channel, software controlled, electromechanical infusion pumps that operate on a volumetric, piston driven, fluid displacement principle. An in-line cassette is used to meter IV fluids through sterile dedicated administration sets designed to be used exclusively with GemStar infusers. Power options included an AC main adaptor, a rechargeable battery pack, a docking station, and two disposable AA alkaline or lithium batteries. The

user interface allows the healthcare practitioner to program fluid delivery through a variety of weight and medication based units. The pump displays provide visible indication of several functions, including active pump operations, alarm and program status, and the parameters of fluid flow. The infusers function as both pole mounted and ambulatory infusion pumps.

As of May 03, 2004, both the infusers and the dedicated GemStar® sets are manufactured and distributed by Hospira Incorporated, formerly the Hospital Products Division of Abbott Laboratories.

All Hospira GemStar® I.V. Infusion Pumps are single channel pumps that are available in the following configurations:

Overview of GemStar® I.V. Infusion Pump Therapies and Configurations		
6 Therapy Pump	6 Therapy Pump	Pain Management Pump
List #: 13000-04	List #: 13100-04	List #: 13150-04
TPN (Total Parenteral Nutrition)	TPN (Total Parenteral Nutrition)	Pain Management Only
Pain Management	Intermittent	
Intermittent	Continuous	
Continuous	Weight-Dosed	
Weight-Dosed	mL/hr Only	
Variable Time	Variable Time	
ML/hr Only		

10. Predicate Device Information:

Infusion pumps cleared for commercial distribution and determined to be appropriate for use as predicates are summarized in the following table.

510(k) #	Product Name	Clearance Date
K023062	Abbott GemStar® Infusion Pump System	09/30/2002
K000821	GemStar® I.V. Infusion Pump	05/24/2000

11. Statement of Substantial Equivalence:

The Hospira GemStar® Infusion Pump System with Hospira GemStar Connect™ is substantially equivalent to the predicate Abbott GemStar® Infusion Pump Systems and Abbott GemStar Connect™ Software based on the following characteristics.

Similarities:

1) Same intended use and indications for use.
2) Same fundamental scientific technology.
3) Same physical, operational, and performance specifications.
4) Same features for programmability of therapy protocols.

12. Comparison to Legally Marketed Device(s)

Factors	Subject Device(s): Hospira GemStar® I.V. Infusion Pump System with Hospira GemStar Connect™	Predicate Device(s): Abbott GemStar® Infusion Pump System
Intended Use	Intended for use in intravenous arterial, subcutaneous, short term epidural infusion and parenteral administration of general I.V. fluids, medications, nutritional fluids, and blood/blood products to a patient.	Same
Indications for Use	Hospital, ambulatory, and home care environments using sterile, dedicated, GemStar® administration sets.	Same
Operating Principle	Volumetric, piston driven, fluid displacement principle. Stepper motor with in-line cassette meters IV fluids through sterile dedicated administration sets. Programmable fluid delivery through a variety of weight and medication based units. Visible indication of several functions, including active pump operations, alarm and program status, and the parameters of fluid flow.	Same
Administration Sets and Fluid Contact Materials	Sterile, dedicated, non-pyrogenic, latex-free "GemStar" administration sets.	Same
Physical Features	Materials, Size, Weight, Input Lines, Output Lines, Power Sources, Battery Type, Power Cord	Same
Environmental Features	Operating Temperature, Storage Temperature, Relative Humidity, Pressure	Same
Performance Features	Delivery Rates, VTBI Range, Dose Units, Delivery Accuracy, Delivery Modes, Therapies, Distal Occlusion Limits, Proximal Occlusion Limits, Alarm Types and Conditions, Default Drug Library.	Same
BioMed Settings	Configuration settings available for customization.	Same
Accessories (Optional)	GemStar Connect™ Remote Communication Software (Clinician Kit, Patient Kit), Docking Station, Bolus Cord, Pole Clamps (2), Battery Pack, Lockboxes (3), AC Mains Adapters (2), Carrying Cases (4) and Carrier, Serial Cable	Same

13. Summary of Substantial Equivalence

The Hospira GemStar® I.V. Infusion Pump System with Hospira GemStar Connect™ as described in this submission is substantially equivalent to the predicate Abbott GemStar® Infusion Pump System with Abbott GemStar Connect™ with respect to:

1) intended use,
2) indication for use,
3) fundamental technology and operating principle,
4) physical, environmental and performance features, and
5) materials of construction for all infuser components and administration sets.

14. Statement of Safety and Effectiveness

The Hospira GemStar® I.V. Infusion Pump System with Hospira GemStar Connect™ meets the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicate Abbott GemStar® Infusion Pump System with Abbott GemStar Connect™.

Prepared and submitted on October 28, 2004 by:

Patricia Melerski

Patricia Melerski
Manager Global Device Regulatory Affairs
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Lake Forest, IL 60045
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Ms. Patricia Melerski
Manager, Global Regulatory Affairs
Hospira, Incorporated
Dept. 389, Bldg. H-2
275 North Field Drive
Lake Forest, Illinois 60045-5045

Re: K042980
Trade/Device Name: Hospira GemStar® Infusion Pump System
Hospira GemStar Connect™ Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 28, 2004
Received: October 29, 2004

Dear Ms. Melerski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K042980

Device Name: Hospira GemStar® Infusion Pump System

Hospira GemStar Connect™ Software

Indications for Use

The Hospira GemStar® Infusion Pump System with Hospira GemStar Connect™ Software is intended for use in intravenous arterial, subcutaneous, short term epidural infusion and parenteral administration of general I.V. fluids, medications, nutritional fluids, and blood/blood products.

The indications for use include hospital, ambulatory, and home care environments. The pump must be used with sterile, dedicated, GemStar® administration sets.

Prescription Use __X__ (Part 21 801 Subpart D) **AND/OR** **Over-The_Counter Use**_____ (Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K042980